Minute Order Form (06/97)

United States District Court, Northern District of Illinois

Name of Assigned Judge or Magistrate Judge	Ronald A. Guzman	Sitting Judge if Other than Assigned Judge	Geraldine Soat Brown
CASE NUMBER	99 C 1492	DATE	3/25/2002
CASE TITLE	Muller vs. Synthes Corp.		

[In the following box (a) indicate the party filing the motion, e.g., plaintiff, defendant, 3rd party plaintiff, and (b) state briefly the nature of the motion being presented.]

MOTION:

DOCKET ENTRY:

(1) ☐ Filed motion of [use listing in "Motion" box above.]

(2) ☐ Brief in support of motion due _____.

(3) ☐ Answer brief to motion due_____. Reply to answer brief due_____.

(4) ☐ Ruling/Hearing on _____ set for _____ at _____.

(5) ☐ Status hearing[held/continued to] [set for/re-set for] on _____ set for _____ at _____.

(6) ☐ Pretrial conference[held/continued to] [set for/re-set for] on _____ set for _____ at _____.

(7) ☐ Trial[set for/re-set for] on _____ at _____.

(8) ☐ [Bench/Jury trial] [Hearing] held/continued to _____ at _____.

(9) ☐ This case is dismissed [with/without] prejudice and without costs[by/agreement/pursuant to]
☐ FRCP4(m) ☐ General Rule 21 ☐ FRCP41(a)(1) ☐ FRCP41(a)(2).

(10) ■ [Other docket entry] For the reasons set out in the Memorandum Opinion and Order, defendants' motion for summary judgment [42-1] is granted and plaintiff's motion for partial summary judgment [47-1] is denied. All matters relating to the referral of this matter having been concluded, the referral is closed and the case is returned to the assigned judge.

Geraldine Soat Brown

(11) ■ [For further detail see order attached to the original minute order.]

	No notices required, advised in open court.		number of notices	Document Number
	No notices required.		MAR 26 2002	
✓	Notices mailed by judge's staff.		date docketed	56
	Notified counsel by telephone.		CDY	
	Docketing to mail notices.		docketing deputy initials	
	Mail AO 450 form.		3/25/2002	
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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

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REBECCA MULLER,	)	
Plaintiff,	)	**Cause No. 99 C 1492**
	)	
v.	)	**Judge Ronald A. Guzman**
	)	**Magistrate Judge Geraldine Soat Brown**
SYNTHES CORP., SYNTHES USA, and SYNTHES SPINE COMPANY, LP,	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

Geraldine Soat Brown, United States Magistrate Judge

The plaintiff in this case alleges defects in a surgical implant device called a cervical spine locking plate ("CSLP"), manufactured by defendants Synthes (U.S.A.) and Synthes Spine Co., L.P. (collectively "Synthes").[1] Plaintiff Rebecca Muller, an Illinois resident, initiated this action in Illinois state court, seeking damages on claims of breach of warranty for particular purpose (Count I), breach of implied warranty of merchantability (Count II), breach of express warranty (Count III),[2] breach of duty to construct the CSLP "in a good and workmanlike manner free of defects" (Count IV), and strict product liability (Count V). (Compl.) [Dkt # 1.] Synthes removed the case to the United States District Court for the Northern District of Illinois, based on diversity jurisdiction. [Dkt # 1.][3]

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[1] Plaintiff initially sued defendants under the incorrect name "Synthes Corp."

[2] Plaintiff has withdrawn Count III for breach of express warranty. (Pl.'s Ans. Mem. to Defs.' Mot. Summ. J. ("Pl.'s Resp.") at 5.) [Dkt # 50.]

[3] Synthes Spine Co., LP is a Delaware limited partnership with its principal place of business in Paoli, Pennsylvania. The general partner of Synthes Spine Co., LP is Synthes Spine, Inc., a Pennsylvania corporation. Synthes (USA), a Pennsylvania general partnership, is one of the limited

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Following removal to federal court, plaintiff filed an amended complaint to add Synthes U.S.A. and Synthes Spine Co., L.P. as defendants (Am. Compl.) [Dkt # 2], and the case proceeded through discovery. After the close of discovery this Court entered an order granting defendants' motion under Fed. R. Evid. 702 to exclude testimony of plaintiff's only two designated experts. *Muller v. Synthes Corp.*, No. 99 C 1492, 2001 WL 521390 (N.D. Ill. May 15, 2001)(Brown, M.J.) [Dkt # 38.] The deadline for plaintiff to disclose experts passed on June 30, 2000 [Dkt # 15], and plaintiff has neither sought leave to disclose additional experts following this Court's May 15, 2001 exclusion order nor has plaintiff deposed defendants' designated experts. (Defs.' Reply Mem. Supp. Mot. Summ J. ("Defs.' Reply") at 3.) [Dkt # 54.] The defendants have filed a motion for summary judgment under Fed. R. Civ. P. 56, and the plaintiff has filed a motion for partial summary judgment on the issue of liability. [Dkt ## 42, 47.] For the reasons set forth below, the Court grants defendants' motion and denies plaintiff's motion.[4] Summary judgment is entered for Synthes and

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partners of Synthes Spine Co., LP. The other limited partners of Synthes Spine Co., LP are individuals, one a citizen of Japan and two others who are citizens of Switzerland. (March 2, 1999 Aff. of Jessie B. Hill, Esq., Director of Legal Affairs of Synthes Spine Co., LP. ¶¶ 5, 6, attached to Defs.' Notice of Removal.) [Dkt # 1.]

[4] Synthes argues that plaintiff's partial motion for summary judgment is deficient not only in substance, which is discussed in the main text of this opinion, but also in form. (Defs.' Resp. to Pl.'s Second Amend Mot. Summ. J. at 3.) [Dkt # 49.] Synthes cites Local Rule 56.1, which states that the movant on a summary judgment motion must, among other requirements of form, attach to the motion all affidavits and other materials referred to in Fed. R. Civ. P. 56(e), submit a supporting memorandum of law, and submit a statement of undisputed facts that makes specific reference to the affidavits, parts of the record, and other supporting materials relied upon to support the assertions of fact. (*Id.* at 2, citing L.R. 56.1(a).) Synthes notes that plaintiff has failed to file a memorandum of law in support of her motion, and that plaintiff's affidavit includes inadmissible scientific or medical opinion, not facts within plaintiff's personal knowledge. (*Id.* at 3-4.) Plaintiff initially sought to file a motion for partial summary judgment on June 11, 2001. [Dkt # 40.] That motion was stricken as not in compliance with Local Rule 56.1, but plaintiff was given leave to file an amended motion. [Dkt # 46.] In particular, plaintiff's initial motion was deficient in that it lacked a statement of material facts. Plaintiff's present motion remedies that prior motion's insufficiency,

against plaintiff on all remaining counts.[5]

BACKGROUND

Plaintiff fell at work and injured her cervical spine on January 6, 1997. (Defs.' Statement of Material Facts ("Defs.' Facts") ¶ 7.) [Dkt # 43.][6] On February 11, 1997, plaintiff underwent a surgical procedure called an anterior cervical diskectomy and fusion to attempt to relieve neck pain resulting from the injury. (Defs.' Facts ¶¶ 12, 14-15, 30.) The surgery was performed by Jerry Bauer, M.D., and consisted of a bone graft fusion of two cervical vertebrae, which included implantation of a supportive metal plate, the CSLP, to hold the bone graft and vertebrae in position while the bone graft set and fused the two vertebrae into a single mass of bone. (Defs.' Facts ¶¶ 14, 17-18.)

The parties agree that once bone fusion is accomplished the CSLP's function is no longer needed. (Defs.' Facts ¶ 19; Pl.'s Ans. to Defs.' Facts ¶ 19 [Dkt # 52].) However, in some bone graft cases fusion can be delayed ("delayed union") or may not occur ("non-union"). (Defs.' Facts ¶¶ 21-22.) The possibility of delay in fusion of the bone graft gives rise to a phenomenon recognized in

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albeit with a fact statement that includes record cites for only nine of 44 paragraphs, and for the most part simply reiterates the fact statement submitted by Synthes. (Pl.'s Statement of Facts Supp. Pl.'s Mot. Summ. J.) [Dkt # 51.] Rather than striking plaintiff's motion again, the Court will consider the deficiencies in plaintiff's submissions as they bear on plaintiff's failure to carry her motion substantively.

[5] The parties have consented to this Court's jurisdiction for the cross-motions for summary judgment, pursuant to 28 U.S.C. § 636(c). [Dkt ## 29, 30.] Accordingly, this Court's Memorandum Opinion and Order is the final ruling on the motions.

[6] Except where indicated otherwise, plaintiff has admitted defendants' statement of material facts in her Answers and Objections to Defendant's Statement of Material Facts. [Dkt # 52.] *See also* Plaintiff's Statement of Material Facts in Support of Motion for Summary Judgment [Dkt # 51], which, with but a few exceptions, is a verbatim reiteration of defendants' statement of material facts.

the medical field as "the implant race." When an implant is attached to human bone a race begins: either the bone heals and relieves stress from the implant, or the implant breaks. (Defs.' Facts ¶ 23.) Plaintiff both admits this phenomenon in response to Synthes' fact statement, and asserts the phenomenon herself in the fact statement accompanying plaintiff's Second Amended Motion for Partial Summary Judgment. (Pl.'s Ans. to Defs.' Facts ¶ 23; Pl.'s Statement of Material Facts Supp. Mot. Summ. J. ("Pl.'s Facts") ¶ 23.)

Synthes states that it includes a printed warning in the packaging of the CSLP, advising the physician to instruct the patient "that a metallic implant is not as strong as a normal, healthy bone and will fracture under normal weight bearing or load bearing in the absence of complete bone healing." (Defs.' Facts ¶ 28.) The printed warning also states:

> **1. * * * <u>These devices are not designed to withstand the unsupported stress of full weight bearing or load bearing</u>.**
>
> **2. <u>These devices can break when subjected to the increased loading associated with delayed union or non-union</u>.**

(Defs.' Facts ¶ 27, and Ex. A.) (Emphasis in original.)[7]

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[7] The text of the warning continues:

> Internal fixation appliances are load sharing devices which hold a fracture in alignment until healing occurs. If healing is delayed, or does not occur, the implant could eventually break due to metal fatigue.* * * The patient should understand that stress on an implant can involve more than weight bearing. In the absence of solid bony union, the weight of the limb alone, muscular forces associated with moving a limb, or repeated stresses of relatively small magnitude, can result in failure of the implant. Notches or scratches put in the implant during the course of surgery may also contribute to breakage.
>
> * * *
>
> 4. * * * Certain degenerative diseases or underlying physiological conditions such as diabetes or rheumatoid arthritis may alter the healing process, thereby increasing the risk of implant breakage.

(Defs.' Facts ¶ 27, and Ex. A.)

While plaintiff denies Synthes' statement, she provides no evidence to the contrary. (Pl.'s Ans. to Defs.' Facts ¶¶ 24-29.) Plaintiff merely states (correctly) that Dr. Bauer "refused to testify about any package inserts" (*i.e.*, the printed warning Synthes claims is included in CSLP packaging) and attending surgeon Steven Mardjetko, M.D. "did not know what [printed warning] was in the specific package" that contained the CSLP used in plaintiff's surgery. (*Id.*)[8] Plaintiff does admit, however, that prior to surgery Dr. Bauer discussed with plaintiff the risks involved in the bone graft procedure, including "failure to fuse" and "failure of instrumentation," although plaintiff contends the failure of instrumentation Dr. Bauer described was potential breakage of screws used to fasten the CSLP in place. (Defs.' Facts ¶ 16; Pl.'s Ans. to Defs.' Facts ¶ 16.)

Plaintiff cites pages 9-15 and 66-67 of Dr. Bauer's deposition as support for this claim that Dr. Bauer only warned plaintiff about the risk of screw breakage. (Pl.'s Ans. to Defs.' Facts ¶ 16.) However, these cited pages of Dr. Bauer's deposition make no reference to any discussions between Dr. Bauer and plaintiff. (Defs.' Facts, Ex. F.) Moreover, although Dr. Bauer testified–and his medical records indicate–that he advised plaintiff of the possibility of "failure of instrumentation," he denies using the phrase "screw breakage" in his discussions with plaintiff. (Defs.' Facts Ex. F at 52; Defs.' Resp. to Pl.'s Statement of Material Facts ("Defs.' Resp. Pl.'s Facts") ¶ 27.) [Dkt # 53.]

Three months after the initial surgery, on May 7, 1997, an x-ray was taken that showed the CSLP was cracked. (Defs.' Facts ¶ 31.) On July 22, 1997 plaintiff underwent a second surgery by Dr. Bauer, in which the cracked plate was removed and replaced with a new CSLP, also manufactured by Synthes. (Defs.' Facts ¶¶ 32, 35.) Prior to this second surgery Dr. Bauer again

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[8] Dr. Bauer testified that he never had occasion to review the package insert that accompanies Synthes products. (Defs.' Facts, Ex. F, Bauer Dep. at 23.)

advised plaintiff of the risks involved, including the possibility of "failure of instrumentation." (Defs.' Facts ¶ 33.) In his post-surgery report Dr. Bauer noted that there was a "fracture through" the CSLP he removed, and he noted that he found "non-union" (presumably of the bone graft meant to fuse the two cervical vertebrae). (Defs.' Facts ¶ 36.)

Ten months after the second surgery, on May 13, 1998, plaintiff underwent an x-ray procedure to evaluate the need for lumbar spinal surgery, which was unrelated to the previous two cervical spine surgeries. (Defs.' Facts ¶ 37.) Coincidentally, this x-ray showed the second CSLP was cracked. (Defs.' Facts ¶ 38.) However, plaintiff was not complaining of any symptoms or problems with her neck, and Dr. Bauer found "no displacement" (presumably of the bone graft of the cervical vertebrae) and no indication the CSLP was "moving or threatening any surrounding structures" or "causing any potential harm or problem." (Defs.' Facts ¶ 39.) Accordingly, the second CSLP was not removed and remains implanted in plaintiff's cervical spine at the present time. (Defs.' Facts ¶ 41.)

Dr. Bauer is not a metallurgist (Pl.'s Facts ¶ 41), and holds no opinion whether either of the two CSLPs implanted in plaintiff was "defective." (Defs.' Facts ¶ 45.) Dr. Bauer has no criticism of the design of the CSLPs, and reports no findings of a metallurgical defect in the two implants. (Defs.' Facts ¶ 43.) Plaintiff concedes that she has no expert who can provide evidence at trial of either manufacturing or design defects in the CSLPs. (Pl.'s Facts ¶ 43; Defs.' Facts ¶¶ 48-49.)

DISCUSSION

Illinois substantive law applies in this diversity action. The procedural requirements for obtaining summary judgment are matters of federal law, set forth in Fed. R. Civ. P. 56. *Ritchie v.*

Glidden Co., 242 F.3d 713, 720 (7th Cir. 2001); *Welge v. Planters Lifesavers Co.*, 17 F.3d 209, 210 (7th Cir. 1994). There are no reported decisions in an Illinois medical implant case with the procedural posture of the present one, where plaintiff's experts already have been excluded prior to the filing of summary judgment motions, and plaintiff not only concedes she has no expert evidence to present at trial, but also has declined to depose defendants' designated experts. Thus, a central issue is whether plaintiff can avoid summary judgment against her (or obtain summary judgment in her favor) on claims either of product liability or breach of warranty without presenting any expert evidence. In short, she cannot.

A. Summary Judgment Standards

Summary judgment is proper "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c); *Cox v. Acme Health Serv., Inc.* 55 F.3d 1304, 1308 (7th Cir. 1995). A genuine issue of material fact exists for trial when, in viewing the record and all reasonable inferences drawn from it in a light most favorable to the non-moving party, a reasonable jury could return a verdict for the non-movant. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986); *Hedberg v. Indiana Bell Tel. Co.*, 47 F.3d 928, 931 (7th Cir. 1995). The movant has the burden of establishing that there is no genuine issue of material fact. *Celotex Corp. v. Catrett,* 477 U.S. 317, 323 (1986). If the movant meets this burden, the non-movant must set forth specific facts that demonstrate the existence of a genuine issue for trial. Fed. R. Civ. P. 56(c); *Celotex,* 477 U.S. at 324. Fed. R. Civ. P. 56(e) mandates entry of summary judgment against a party "who fails to make a showing sufficient to

establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex,* 477 U.S. at 322. A scintilla of evidence in support of the non-movant's position is not sufficient to oppose a summary judgment motion. "There must be evidence on which the jury could reasonably find for the [non-movant]." *Anderson,* 477 U.S. at 252.

B. Breach of Warranty of Fitness for Particular Purpose

Count I of plaintiff's complaint alleges that the fact the two CSLPs broke constitutes a breach of warranty of fitness for a particular purpose. (Am. Compl. ¶ 7.) Illinois adopts the definition of the Uniform Commercial Code ("UCC") that an implied warranty of fitness for a particular purpose exists where:

> [T]he seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods.

810 Ill. Comp. Stat. § 5/2-315 (2000). *McConnell v. Arrow Uniform Rental, Inc.,* No. 97 C 6551, 1999 WL 92908, at * 9 (N.D. Ill. Feb. 17, 1999)(Coar, J.) The statute defines a "contract for sale" as including "both a present sale of goods and a contract to sell goods at a future time." 810 Ill. Comp. Stat. § 5-2/106. A "sale" in turn is defined as "the passing of title from the seller to the buyer for a price." *Id.*

To avoid summary judgment in defendants' favor on Count I (or to obtain summary judgment on plaintiff's partial motion), plaintiff must demonstrate a question of material fact as to one or more of (or prove all of) the following elements: 1) that supplying the CSLPs constituted a sale of goods by Synthes to plaintiff; 2) that Synthes had reason to know the particular purpose for which plaintiff required the goods; 3) that plaintiff relied on the skill and judgment of Synthes in selecting the

CSLPs for her implant procedure; and 4) that the CSLPs were not fit for the particular purpose for which they were used. *McConnell v. Arrow Uniform Rental*, at * 9, *citing Federal Ins. Co. v. Village of Westmont,* 649 N.E.2d 986, 990 (Ill. App. 1995); *see also Malawy v. Richards Mfg Co.,* 501 N.E.2d 376, 382 (Ill. App. 1986)(implied warranty claim regarding surgical implant of plate).

Synthes contends plaintiff has no evidence that Synthes sold the CSLPs *to plaintiff*, or that Synthes had any reason to know the particular purpose for which plaintiff required the CSLPs, or that plaintiff relied on the skill and judgment of Synthes–rather than that of her surgeon, Dr. Bauer–in selecting the CSLPs for her bone graft surgery, or indeed that Synthes, rather than Dr. Bauer, was the one who selected the CSLPs for plaintiff. (Defs.' Mem. Supp. Mot. Summ. J. ("Defs.' Mem.") at 2.) [Dkt # 42.] In response plaintiff contends that "a lack of privity of contract is not a defense in this type of action." (Pl.'s Resp. at 2.) Plaintiff cites for this proposition *Suvada v. White Motor Co.*, 210 N.E.2d 182, 185 (Ill. 1965). The citation is inapt, however. In *Suvada*, the Illinois Supreme Court announced its adoption of strict product liability as a tort remedy distinct from contract-based breach of warranty claims. *Suvada* gave the buyer of a defective product the right to seek recovery directly against the manufacturer, despite there being no privity between the parties and thus no basis for a breach of warranty claim (*id.*), however, *Suvada* emphasizes plaintiff's difficulty in asserting a breach of warranty claim against a manufacturer with which plaintiff personally had no direct dealings.

In her own summary judgment motion, plaintiff attaches a portion of a hospital medical bill apparently addressed to plaintiff relating to the February 1997 surgery. (Pl.'s Second Am. Mot. Partial Summ. J. ("Pl.'s Mot.") Unnumbered Ex.) [Dkt # 47.] Plaintiff's statement of material facts cites the document as proof that plaintiff paid "approximately $2,500 for each of the Synthes plates

and screws." (Pl.'s Facts ¶ 44.) As Synthes notes in its response to plaintiff's motion, the invoice refers only to sale of one implant device, and there is no proof plaintiff paid the invoice. (Defs.' Resp. Pl.'s Facts ¶ 44.) More importantly, this unauthenticated, partial document indicates the bill for services was sent by Lutheran General Hospital, not Synthes. (The exhibit document also cuts off all of the bill addressee's name except "J. Muller.") The exhibit provides no competent evidence that plaintiff purchased the CSLPs directly from Synthes, which would suggest privity between the parties, and, indeed, indicates that plaintiff purchased this particular CSLP from Lutheran General Hospital, not Synthes.[9]

There also is no evidence that Synthes knew its product was to be used in plaintiff's bone graft surgery, or knew what expectations, if any, plaintiff placed on the longevity or other performance attributes of the CSLP implanted in her. Plaintiff argues that Synthes had such knowledge (*see, e.g.*, Pl.'s Resp. at 2), but offers no admissible evidence to support these arguments.[10] On the contrary, plaintiff admits Dr. Bauer warned her of possible "failure of

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[9] This hospital bill is one of several documents plaintiff attaches to her motion for summary judgment for which plaintiff provides no authentication. Such unattested documents are insufficient to create a question of fact or establish required proof in a summary judgment motion. *Martz v. Union Labor Life Ins. Co.*, 757 F.2d 135, 138 (7th Cir. 1985).

[10] Plaintiff attaches to her summary judgment motion her own affidavit. The document is undated, and is neither attested by a notary nor even signed by plaintiff. Accordingly, its form technically is inadequate to establish plaintiff's averments as competent evidence either to oppose Synthes' summary judgment motion or to support plaintiff's own motion. Fed. R. Civ. P. 56(e); *Henderson v. Clark Oil and Refining Corp.*, 639 F. Supp. 105, 108 (N.D. Ill. 1986)(Grady, J.) Even were this affidavit properly admissible, it does not help plaintiff. Indeed, the affidavit contains an admission against plaintiff's own interest. The affidavit avers: "I was not notified of any written warranty or disclaimer with respect to the [CSLPs] at any time prior to the operations." (Pl.'s Mot., Muller Aff. ¶ 7.) There is no averment that plaintiff stated to anyone her expectations as to how the CSLPs would perform, but merely a representation that no performance warranties were given to her. Thus, plaintiff cannot claim either that she sought to advise Synthes–or anyone–that she wanted a plate that would never crack, nor can she claim that anyone gave her a warranty that the CSLPs implanted in her never would crack.

instrumentation" prior to both implant surgeries. There is no evidence to demonstrate that she reasonably expected the implants would not break, or that somehow she communicated to Synthes that her agreeing to the implant of Synthes' products was based on such an expectation.

Thus, plaintiff submits no evidence to prove the first three elements of the claim for breach of warranty of fitness for a particular purpose. As to the fourth element, whether the CSLPs were fit for the particular purpose for which they were used, apparently plaintiff is arguing that the fact of breakage alone demonstrates lack of fitness. Plaintiff sums up her breach of warranty of fitness argument in this way:

> What the Defendant has avoided in his brief, and throughout the case, is the fact that two titanium plates inserted into the body of Rebecca Muller broke. What the Defendant has failed to produce is an explanation for the breakage.

(Pl.'s Resp. at 3.) In fact, it is the plaintiff's burden, not the defendants', to produce evidence that by breaking at all, for whatever reason, the CSLPs failed to conform to the standard for plate implants. If it is expected that a CSLP is likely to fail sooner or later, the fact that the plates ultimately broke can not, of itself, prove that the plates were unfit for their purpose. It is undisputed that plaintiff's second bone graft was successful even though the second plate, like the first, ultimately broke. If plaintiff is arguing that the plates failed prematurely, plaintiff cannot prove this without expert testimony regarding what constitutes "fitness" in this type of surgical implant.

The question of the design parameters of a medical implant, and particularly how long a CSLP should hold up before breaking, is one that goes beyond the knowledge that the average lay person reasonably could be expected to possess. Accordingly, competent proof on this issue requires expert testimony. This requirement is often stated in product liability cases. *See, e.g., Baltus v. Weaver Div. of Kidde Co.,* 557 N.E.2d 580, 588-89 (Ill. App. 1990)(whether manufacturing

negligence results in unreasonably dangerous product "seems particularly appropriate for expert opinion"); *Dancy v. Hyster Co.,* 127 F.3d 649, 653 (8th Cir. 1997)(lay jurors may be able to understand that product does not work, but "are not likely to possess 'common understanding' about how products are designed"); *Minisan v. Danek Medical, Inc.,* 79 F. Supp. 2d 970, 975 (N.D. Ind. 1999)(Sharp, J.)(proof of legal causation in medical device cases must be by expert testimony stated in terms of reasonable probability). Although these cases involve strict product liability claims, the same reasoning used to require expert testimony in defective product claims also applies in the present case, where plaintiff concedes it is reasonable to expect the CSLPs will break eventually, if plaintiff seeks to prove that the CSLPs produced by Synthes were not fit because they did not last as long as such a product should reasonably be expected to last.

Plaintiff notes there is one Illinois case specifically concerning breach of warranty in a medical implant case holding that to prove breach of warranty the plaintiff does not have to prove the product was "defective." (Pl.'s Resp. at 2, citing *Malawy v. Richards Mfg. Co.,* 501 N.E.2d 376, 383 (Ill. App. 1986).) *Malawy* does state that it is not necessary to prove a defect in a claim for breach of implied warranty, where "the pivotal inquiry as to liability . . . is whether the product conforms to the standards of merchantability or fitness established by the contractual relationship." *Id.* at 383. The plaintiff must still prove that the product was unfit for the particular purpose when it left the manufacturer's control. *Id.*[11] Plaintiff has not made such proof, nor can she do so without

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[11] As Synthes correctly points out (Defs.' Mem. at 2-3), not all Illinois courts agree with *Malawy's* statement that the plaintiff need not prove "defect" in a breach of warranty case. *See, McConnell v. Arrow Uniform Rental, Inc.,* 1999 WL 92908, at * 9, comparing *Malawy* with *State Farm Fire and Casualty Co. v. Miller Elec. Co.,* 562 N.E.2d 589, 596 (Ill. App. 1990). The court in *State Farm v. Miller Elec.* stated:

We . . . decline to follow the rationale espoused in *Malawy.* Instead, we agree with

expert testimony, which she has admitted she does not have now and will not introduce at trial. Accordingly, Synthes is entitled to summary judgment in its favor on plaintiff's Count I claim of breach of implied warranty of fitness for a particular purpose.

C. Breach of Warranty of Merchantability

Lack of expert testimony also defeats plaintiff's Count II claim for breach of warranty of merchantability. The relevant portions of the Illinois UCC statute provide that a breach of implied warranty of merchantability requires a showing: (1) that there is a contract for sale between the parties; (2) the seller is a merchant with respect to goods of that kind; and (3) the goods are not fit for the ordinary purposes for which such goods are used. 810 Ill. Comp. Stat. § 5/2-314(1) and (2)(c); *Federal Ins. Co. v. Village of Westmont,* 649 N.E.2d 986, 990 (Ill. App. 1995).[12]

> the line of cases which has recognized the inherent similarities between implied warranty of merchantability and strict liability causes of action. While these causes of action are not exactly identical, these cases have determined that the existence of a defect in a product is a necessary requirement to prevail under either theory.

562 N.E.2d at 596, citing cases. The *McConnell* court found it unnecessary to resolve the apparent conflict between *Malawy* and *State Farm*, deciding that the plaintiff failed to show the defendant had knowledge of the particular purpose for which the plaintiff selected the product, and failed to show the plaintiff relied on the defendant in making the selection. *McConnell*, at * 9. Likewise, it is not necessary in this case to resolve any conflict between *Malawy* and *State Farm*.

[12] Section 5/2-314(2) provides:
Goods to be merchantable must be at least such as:
(a) pass without objection in the trade under the contract description; and
(b) in the case of fungible goods, are of fair average quality within the description; and
(c) are fit for the ordinary purposes for which such goods are used; and
(d) run, within the variations permitted by the agreement, of even kind, quality and quantity within each unit and among all units involved; and
(e) are adequately contained, packaged, and labeled as the agreement may require; and
(f) conform to the promises or affirmations of fact made on the container or label if any.

As discussed above, plaintiff has failed to demonstrate that there was a contract for sale between Synthes and plaintiff. Even assuming, *arguendo*, that plaintiff were able to demonstrate that she has standing to sue for breach of warranty of merchantability, there is the further critical question of whether any evidence has been brought forth demonstrating that the CSLPs implanted in plaintiff were not "fit for the ordinary purposes for which such goods are used." Plaintiff has produced no evidence that the two CSLPs implanted in her were in any way different from other CSLPs that are accepted in the trade. Plaintiff's sole argument that they are not fit is the fact that they broke. However, plaintiff effectively admits that the ordinary purposes for implants are circumscribed by the "implant race." That is, given a long enough delay in the healing process, the implant may be expected to lose the race and break. There is no evidence to demonstrate that these CSLPs broke earlier than is reasonably standard for CSLPs. Accordingly, summary judgment is entered against plaintiff on the claim of breach of implied warranty of merchantability.

D. Negligent Manufacture

Plaintiff's Count IV apparently is brought on a theory of negligence, since it alleges a breach of a "duty to construct" the CSLPs "free of defects."[13] (Am. Compl. Ct. IV ¶¶ 4, 7.) Although plaintiff alleges breach of a duty to "construct," her complaint does not specify whether she asserts Synthes was negligent in the manufacturing process, or in the design process, or both. However, in her partial motion for summary judgment plaintiff contends that the CSLPs "were manufactured *and*

[13] Synthes questions whether Count IV is meant to be a negligence claim, or another breach of warranty claim, or another strict product liability claim. (Defs.' Mem. at 7.) Plaintiff does not state expressly what type of claim this count is intended to be, either in the complaint itself or in her various briefs. This section assumes that plaintiff intends a negligence claim. If plaintiff intends Count IV to be a breach of warranty claim, her claim fails for the same reasons discussed previously as to Counts I and II.

designed for the purpose of insertion into the human body." (Pl.'s Mot. ¶ 6. Emphasis added.) Synthes argues the claim as if it concerned negligent design (Defs.' Mem. at 8), and plaintiff takes up this argument in her response (Pl.'s Resp. at 5). Accordingly, the Court will discuss Count IV in the context of negligent design.

To prove a claim for negligence, plaintiff must show Synthes owed a duty to plaintiff, Synthes breached its duty, and plaintiff suffered an injury proximately resulting from that breach. *McConnell v. Arrow Uniform Rental,* 1999 WL 92908, at * 6, citing *Cunis v. Brennan,* 308 N.E.2d 617, 618 (Ill. 1974). "[N]egligence does not permit liability without fault." *Baltus v. Weaver Div. of Kidde Co.,* 557 N.E.2d at 586. Accordingly, where plaintiff claims negligent manufacture based on defective design, she must establish that Synthes "deviated from the standard of care that other manufacturers of [spinal bone plates] followed at the time the [CSLP] was designed," or show that Synthes knew or should have known, in the exercise of ordinary care, that the CSLP "was unreasonably dangerous and [Synthes] failed to warn of [the CSLP's] dangerous propensity." *Id.* If plaintiff contends the CSLP design is "unreasonably dangerous," she also must present evidence of "an alternative design which is economical, practical and effective." *Id.* at 585. Further, plaintiff must establish "a credible basis for a reasonable inference that a condition of the product proximately caused [her] injury and for elimination of reasonable secondary causes." *Id.* at 587. "No inference of defectiveness arises from the mere fact that an injury occurred." *Id.*

In *Baltus* where the issue was whether the design of a mechanical part was defective, the court concluded that proof of a breach in the standard of care required expert testimony. Where the issues "involve specialized knowledge or expertise outside the layman's knowledge," "[m]anufacturing negligence resulting in an unreasonably dangerous product seems particularly

appropriate for expert opinion." *Id.* at 588-89. Without testimony from an expert "the jury would be left to speculate" about whether the design made the product unreasonably dangerous. *Id.* at 590.

The mere fact plaintiff's CSLPs both cracked does not lead to an obvious conclusion of defective design that would be within a jury's common understanding and experience. *Id.* at 589. Conclusions about the standard of care for designing cervical bone plates, alternative designs that would compensate for the purported unreasonably dangerous potential that the CSLP might crack, and whether the cracks in the two particular CSLPs implanted in plaintiff were the proximate cause of plaintiff's claimed injury cannot be reached by a finder of fact based merely on a lay person's knowledge and experience.

The difficulty in proving proximate causation is illustrated by the sequence of events here, where the treating physician reported "non-union" of the bone graft when the first CSLP implant was found to be cracked and was replaced, but did not report a similar failure of the bone graft to heal when the second CSLP was found to be cracked. Plaintiff presents no evidence as to whether the crack in the first CSLP was the proximate cause of non-union after the first implant, or whether the successful healing after the second implant could not be attributed, at least in part, to the second CSLP, even though the second device was subsequently found to have cracked. Evidence from a qualified expert is required to resolve these matters, expert testimony which plaintiff admittedly cannot provide. Without the prospect of expert testimony, plaintiff could not produce at trial evidence to answer or prove these questions. The trier of fact would have to speculate how to resolve them. "It is well-settled that speculation may not be used to manufacture a genuine issue of fact." *Amadio v. Ford Motor Co.,* 238 F.3d 919, 927 (7th Cir. 2001).

Where the testimony of plaintiff's designated expert is excluded, plaintiff cannot raise a

question of fact to avoid summary judgment (or show entitlement to summary judgment in her favor) as to matters for which plaintiff's only evidence is excluded testimony. *See, e.g., Kirstein v. W.M. Barr & Co., Inc.,* 983 F. Supp. 753, 761 (N.D. Ill. 1997)(Conlon, J.)(plaintiff suffered burns to his feet when solvents he was using to remove linoleum adhesive caught fire; summary judgment granted for defendants after the court disqualified plaintiff's expert and rejected plaintiff's claim that evidence of his burns was sufficient by itself to raise a question of fact whether the solvents were defective.) As in *Kirstein*, evidence of cracked CSLPs is not sufficient by itself to raise a question of fact–or to prove–that the CSLPs were defective.

Plaintiff contends that her burden of proof is satisfied on the negligent design issue by referring to "a large box containing the known claims of breakage" of the CSLP, and documents comprising in-house reports from Synthes about these breakage claims. Plaintiff asserts this evidence "clearly show[s] that Defendant knew of numerous instances of plate breakage." (Pl.'s Resp. at 6.) Although plaintiff states that written reports evidencing breakage of 66 CSLPs, are attached to her response brief, plaintiff's response in fact includes neither copies of any reports, nor evidence of the "large box."

There is only one report of a CSLP "malfunction" attached to plaintiff's partial motion for summary judgment. This unauthenticated document is titled "1998 Database Complaints," and indicates it was "Produced by Synthes." However, the document relates only one claimed breakage of a CSLP, which was reported January 19, 1998 by plaintiff's counsel in this case, Richard Goldner. (Pl.'s Mot. Unnumbered Ex.) Even were this document admissible, which it is not (see footnote 9), it is insufficient either to prove plaintiff's contention that Synthes knew the CSLP design was unreasonably dangerous, or to raise a question of fact to defeat defendants' summary judgment

motion as to whether the CSLP design in fact was unreasonably dangerous, or whether Synthes knew or with the exercise of ordinary care should have known of the unreasonable danger allegedly posed by the design. Thus, Synthes is entitled to summary judgment in its favor on the Count IV negligent design claim.

E. Strict Product Liability

The same problems also doom plaintiff's Count V claim for strict product liability. Count V alleges the CSLPs were "unreasonably dangerous when [they] left the control of Defendants and the condition was the proximate cause of the Plaintiff's injuries." (Am. Compl. Ct. V ¶ 4.) This count apparently means to assert a claim of strict product liability.

Under Illinois law, to prove a claim for strict product liability the plaintiff must show: (1) the injury resulted from a condition of the product; (2) the condition was unreasonably dangerous; (3) the condition existed at the time the product left the manufacturer's control. *Kirstein v. W.M. Barr & Co., Inc.*, 983 F. Supp. at 760; *Ralston v. Casanova*, 473 N.E.2d 444, 449 (Ill. App. 1984). To prove the condition of the product is unreasonably dangerous, the claimant must show: (1) a design or manufacturing defect; or (2) a failure to warn of a danger posed by the product of which the average consumer would be unaware. *Kirstein*, 983 F. Supp. at 760.

The previous section has analyzed why plaintiff cannot show a manufacturing defect related to design issues. The same analysis applies to a defect in the fabricating of the CSLPs. Plaintiff has no evidence to prove there was a defect in the fabricating process. Nor can she prove the CSLPs were defective at the time they left the control of Synthes, nor that a defect in fabrication proximately caused plaintiff's alleged injuries, nor that the CSLPs otherwise were unreasonably dangerous.

As to product warnings on medical devices, Illinois employs the "learned intermediary doctrine." *Hansen v. Baxter Healthcare Corp.*, 723 N.E.2d 302, 311 (Ill. App. 2000). Under this doctrine, the intended audience for product warnings is not the patient on whom the device ultimately is used. Instead, the manufacturer of a medical device has "a duty to warn physicians of . . . a device's dangerous propensities, and physicians, in turn, using their medical judgment, have a duty to convey any relevant warnings to their patients." *Id.* Moreover, the manufacturer's duty to warn arises only where the danger is not commonly appreciated. *Id.* Where the risk is one of which the medical community generally is aware, the manufacturer does not have to warn individual physicians about that risk. *Id.* at 312.

In the present case, Synthes includes with its motion for summary judgment copies of the printed warnings that Synthes inserts in the CSLP package. (Defs.' Facts ¶¶ 24-29, and Ex. A.) Dr. Bauer, plaintiff's primary doctor for the CSLP implants, denied ever reviewing these inserts, and declined either to read them or to say anything at his deposition about them. (Defs.' Facts Ex. F at 23-24.) However, Dr. Bauer did testify that he advised plaintiff prior to both operations that the risks of the implant surgery included possible "failure of instrumentation." (Defs.' Facts ¶¶ 16, 33.)

Dr. Bauer's testimony that he never reviewed the Synthes package insert warnings does not raise a question of material fact about whether Synthes in fact included such warnings in the CSLP packaging or whether they were inaccurate. On the contrary, a reasonable inference from the fact Dr. Bauer gave plaintiff the "failure of instrumentation" warning is that Dr. Bauer was aware generally of the risk that devices implanted in the body might fail under normal stresses.

Accordingly, Synthes is entitled to summary judgment on plaintiff's strict product liability claim.

CONCLUSION

For the foregoing reasons, defendants' motion for summary judgment [Dkt # 42] is GRANTED and plaintiff's motion for partial summary judgment [Dkt # 47] is DENIED.

IT IS SO ORDERED.

GERALDINE SOAT BROWN
United States Magistrate Judge

DATED: March 25, 2002